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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,545	01/05/2004	Otmar Klingler	DEAV2003/0002 US NP	2394
5487	7590	03/26/2007		
ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER RAO, DEEPAK R	
			ART UNIT	PAPER NUMBER
			1624	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/26/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/26/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

Application No.

10/751,545

Applicant(s)

KLINGLER ET AL.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 ~~is~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 ~~is~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

This office action is in response to the arguments filed on December 13, 2006.

Claims 1-9 are pending in this application.

***The following rejections are maintained:***

1. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barvian et al., WO 02/064571. The reasons provided in the previous office action are incorporated here by reference. (The reasons from the previous office action are provided below for convenience):

The reference teaches a generic group of pyrimidine-4,6-dicarboxylic acid diamide compounds which embraces applicant's instantly claimed compounds. See the structural formula I in page 2; the subgeneric formula III in page 4 and formula V in page 5 wherein Ar is defined as aryl or Het, unsubstituted or substituted. The reference further, provides examples of heteroaryl groups included within the recitation of Het in page 10, including pyridyl, furanyl, indolyl, ..., benzo-2,1,3-thiadiazole, etc. The reference specifically discloses compounds wherein the Het is benzo-2,1,3-thiadiazole, see the compound disclosed in page 5, lines 27-28 and page 6, lines 1-2 (structural formulae were depicted in page 10 of the previous office action). The reference teaches a process to prepare the compounds, see the reaction scheme in page 18. The reference compounds are taught to be useful as pharmaceutical therapeutic agents having MMP-13 inhibitor activity, see the abstract. The instant claims differ from the reference compounds by reciting a more limited subgenus than the reference, for example, the instant claims recite specific heterocycles as represented by the term Het; or the instant claims recite specific substituent R<sup>11</sup> for the aryl group. The reference generically teaches substituents such as T(CH<sub>2</sub>)<sub>m</sub>CO<sub>2</sub>R<sup>4</sup> for the aryl groups, which substituents are analogous to the substituent groups recited for R<sup>11</sup> in the instant claims. Further, the reference defines the term Heteroaryl to include heterocycles such as pyridyl, furanyl, ... benzo-2,1,3-thiadiazolyl, etc. (see page 10). Thus, the reference teaches the

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equivalency of various substituent groups as these are taught to be alternatives. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the substituent groups of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select any of the substituents from the genus in the reference to prepare the instant compounds, because the reference teaches that the substituents are equivalent as they are disclosed to alternatives and the skilled artisan would have had the reasonable expectation that such compounds would have similar properties and therefore, the same use. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the reference compounds have an undesirable property of being praline hydroxylase inhibitors and thus do not have selective MMP 13 inhibiting properties of the compounds of the present invention'. Applicant further, relies on the data in page 37, Table 3 of the present specification. The data in Table 3 of the specification, however, provides that "pyrimidine-4,6-dicarboxylic acid" was tested and compared with some of the examples of the present invention, which are drawn to 'pyrimidine-4,6-dicarboxamide' compounds. The comparative data is not provided for structurally analogous compounds and instead, the provided data compares 'dicarboxylic acid' compound with 'dicarboxamide' compounds. Therefore, this data in Table 3 relied upon is not seen to be referring to structurally analogous compounds. In the absence of sufficient evidence clearly demonstrating the unexpected properties of the instantly claimed compounds, the rejection under 35 U.S.C. 103 is maintained.

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2. Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,933,298.
3. Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/700,273.

The reasons provided in the previous office action are incorporated here by reference. Applicant's request that 'these rejections be deferred pending identification of allowable subject matter' is acknowledged.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

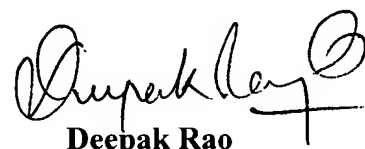
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

March 18, 2007